

### **REMARKS**

Claims 1, 2, 4-27 and 29-31 have been amended. The amendment to claim 1 finds representative support in the specification at, for example, paragraph [0077]. The amendments to claims 2, 4-27 and 29-31 address an objection of record and replace "A" with "The" at the beginning of each claim. These amendments are formalistic in nature and do not add prohibited new matter. Claim 21 has been further amended to delete the phrase "or similar" in describing the recited monomers. Claims 19 and 20 have been canceled without prejudice or disclaimer of the encompassed subject matter.

#### **1. Commonly Assigned Applications**

The Examiner's attention is called to the following table of what may be considered to be technically related U.S. patent applications of Applicants' assignee. The current status of each application as reported in the PAIR database is given in the right-hand column. Each of the published U.S. and PCT applications has been listed on a form PTO-1449 attached to a previously filed Information Disclosure Statement.

It is assumed that the Examiner has ready electronic access to each of the listed U.S. applications, but the undersigned will provide a copy of any document from these files if requested by the Examiner.

<b>Application No.</b>	<b>US Publication No.</b>	<b>PCT Pub.</b>	<b>Status</b>
10/512,440 October 25, 2004	US 2006-0034816 February 16, 2006	WO 2003/090800 November 6, 2003	Notice of Allowance mailed January 22, 2010
11/044,715 January 28, 2005	US 2005-0181026 August 18, 2005	WO 2004/108176 December 16, 2004	Final Rejection mailed October 21, 2009
10/557,991 November 22, 2005	US 2006-0281165 December 14, 2006	WO 2004/108917 December 16, 2004	Abandoned
10/587,547 July 28, 2006	US 2007-0190122 August 16, 2007	WO 2005/072783 August 11, 2005	Abandoned
10/587,420 July 28, 2006	US 2007-0148117 June 28, 2007	WO 2005/072784 August 11, 2005	Abandoned
12/750,255 March 30, 2010	US 2007-0148117 June 28, 2007	WO 2005/072784 August 11, 2005	Ready for Examination
11/886,008 April 11, 2008	US 2009-0081279 March 26, 2009	WO 2006/095193 September 14, 2006	Ready for Examination
12/373,919 February 3, 2009	US 2009-0169600 July 2, 2009	WO 2008/009925 January 24, 2008	Ready for Examination

**2. Rejection under 35 U.S.C. 112, first paragraph**

Claims 1, 2, 4-27 and 29-31 are rejected for allegedly failing to comply with the written description requirement due to the recitation in claim 1 of "an unused skin dressing". The Examiner asserts that the specification does not specify "unused" and that the term is not explicitly defined.

Applicants submit that it is clear from the specification of the subject application that the term "unused" relates to the state of the dressing prior to use, *i.e.*, in an unused form. Applicants point the Examiner to the following representative paragraphs:

[0027] ("The dressing components are kept separate **before use**, e.g. by being sealed in separate sterile, water-impervious packages...." (emphasis added));

[0028] ("**In use** of the dressing, the second dressing component is located on the skin of a human or animal...." (emphasis added));

[0097] ("...the dressing components 16 and 18 are kept separate **before use**, e.g. being sealed in separate, sterile, water-impervious packages such as laminated aluminium foil pouches." (emphasis added));

[0098] ("**In use** of the dressing, when the first component 16 contacts the second component 18, water rapidly migrates from the second component to the first component..." (emphasis added)).

Applicants submit that although the term "unused" is sufficiently defined in the specification (as indicated above), it does not require explicit definition because it is clear and readily understandable to laypersons as well as those of ordinary skill in the art. Moreover, the employment of the term "unused" in claim 1 goes beyond simply a statement of intended use. Rather, the term "unused" defines the structure and condition of the dressing prior to its use. While art such as U.S. Patent 4,327,731 to Powell might describe a somewhat similar structure at some stage of use, the similarity does not arise, at the very least, when the Powell structure is in an unused condition. Applicants therefore submit that the term "unused" provides a clear structural distinction over the prior art and respectfully request that this rejection be withdrawn.

**3. Rejection under 35 U.S.C. 112, second paragraph**

Claims 19 and 20 are rejected as indefinite due to the recitation that the first and second dressing components include polymers that are functionally similar to each other in terms of hydration.

Claim 21 is rejected as indefinite because the Examiner asserts that it is unclear as to the metes and bounds of the monomers encompassed by the claim.

Without acquiescing to the merits of the Examiner's rejection, Applicants have canceled claims 19 and 20 without prejudice or disclaimer of the encompassed subject matter, thereby mooting the rejections as they apply to these claims. Applicants have also amended claim 21 to remove the contested "similar to" language. Accordingly, Applicants respectfully request that this rejection be withdrawn.

**4. Rejection under 35 U.S.C. 102(b)**

Claims 1, 2, 4, 6, 7, 12, 22 and 26 are rejected as allegedly anticipated by U.S. Patent 4,327,731 to Powell ("Powell") in light of U.S. Patent 4,581,336 to Malloy *et al.* ("Malloy") and U.S. Patent 4,665,028 to Amotz ("Amotz") for the reasons provided on pages 4-6 of the Office Action.

Applicants note that the Examiner has cited Malloy and Amotz to support the Examiner's assertion that the disclosure in Powell of impregnating layers with enzyme (e.g., at column 4, line 28) results in a layer carrying immobilized enzyme. In particular, the Examiner refers to a passage in Malloy which states that "...glucose oxidase was immobilized thereon by impregnating the treated support with a solution containing...glucose oxidase..." (column 20, lines 3-6). Applicants point out, however, that the passage goes on to state that the immobilization was effected for a period of 1.5 days, which the Examiner appears to have overlooked.

The Examiner further refers to the disclosure at the bottom of column 3 of Amotz which refers to immobilizing enzyme by impregnating a carrier with enzyme solution. However, this passage goes on to refer to the addition of a cross-linking agent.

Thus, reading the disclosures of Malloy and Amotz properly in context, Applicants submit that Malloy and Amotz do not in any way support the Examiner's view that Powell discloses immobilized enzyme. Applicants also point to the first paragraph of column 3 of Powell in which it is stated that the absorbent material is also impregnated with a substrate material (lines 5-6) and that the substrate is released in the presence of moisture (line 11). The impregnated substrate is

therefore clearly not immobilized. As examples of widely used methods in which proteins are absorbed into paper and do not become immobilized, Applicants point to experiments that utilize absorbent paper as a means of collecting samples of liquid (e.g., biological fluids) containing various proteins. Typically, these proteins are to be released again from the paper for subsequent analysis or experimentation, even after the paper has been allowed to dry. Moreover, if the enzyme has been dried in a manner so as to retain its enzyme activity, then it is unlikely that it will have degraded (denatured) sufficiently to become irreversibly adsorbed onto the fibers of the absorbent carrier. Other types of absorbent materials and structures are commonly used for collecting and releasing fluids that contain proteins in which the proteins must not become immobilized, including cotton swabs, fabric discs, porous plastic strips, etc. In forensic science, there are many examples in which biological fluids are simply eluted from porous structures, especially from clothing fabric. As evidence of the use of absorbent paper in the sampling of protein solutions in which it is clear that the protein is not immobilized, Applicants provide for the Examiner's consideration a selected passage from a journal reference from 1957 (**Exhibit A**) in which it is disclosed that the antibodies were allowed to elute from the paper discs after the paper discs were allowed to dry. In these situations, it is clear that impregnation of a porous/absorbent structure with a protein solution does not lead to protein immobilization.

In contrast, in immunoassay, it is common for absorbent structures to hold proteins such as antibodies, antigens and enzymes at particular locations within the absorbent material. In these instances, special measures are taken to ensure that the proteins are immobilized, such as by using well known chemical cross-linking agents to immobilize the protein. Alternatively, proteins of interest can be chemically coupled to an immobilizing substance, such as a cellulose binding domain, which attaches itself to cellulose fibers such as those found in paper structures.

Powell does not teach immobilizing either of the two enzymes used (oxidase and peroxidase) to the materials used to construct the moisture detecting device. A person of ordinary skill in the art must then conclude that it is sufficient to merely impregnate the absorbent material with the enzymes. Such a person would have no reason to believe that impregnation with the protein (enzyme) solution would involve immobilization, especially as this term is used to describe the incorporation of glucose and chromogen into absorbent materials, and it is necessary for these components not to be immobilized. Moreover, there is no advantage whatsoever in immobilizing the enzymes for the purposes of this invention. To effect a visible color

change, it is necessary for all of the ingredients to mix intimately, and this would not be better accomplished by immobilizing the enzymes. Applicants submit that there is nothing to be gained by maintaining a layered or compartmentalized construction once water has entered the system.

On the question of immobilization (page 10 of the Office Action), the Examiner asserts that WO 01/28600 to Green ("Green") teaches enzyme immobilization, so that it would allegedly be obvious to use immobilized enzymes in Powell. Applicants have already pointed out in the previously filed response of April 6, 2009 that enzyme immobilization adds considerably to both processing steps and costs, and as such, would not be employed without an envisioned benefit. Applicants submit that no benefit would be obtained by immobilizing the enzymes in Powell so there would be no rationale for a person of ordinary skill in the art to use immobilized enzymes.

At least for the above reasons, Applicants respectfully request that the rejection of the claims as anticipated be withdrawn.

**5. Rejection under 35 U.S.C. 103(a)**

Claims 1, 2, 4-27 and 29-31 are rejected as obvious over Powell, Malloy and Amotz in view of WO 01/28600 to Green ("Green"), U.S. Published Application No. 2002/0037270 to Munro *et al.* ("Munro") and U.S. Patent 5,483,697 to Fuchs ("Fuchs") for the reasons provided on pages 6-9 of the Office Action.

Applicants note that this rejection is essentially the same as the one asserted in the previous office action and refer the Examiner to the rebuttal arguments submitted by Applicants in the subsequent response filed on April 6, 2009. In that response, Applicants pointed out the oxygen transport function achievable with the claimed dressing (as also described in the specification at, for example pages 16 and 17 (at paragraphs [0073] to [0077])).

The Examiner states on page 10 of the Office Action that Applicants' claims do not contain the feature of oxygen transport. To more clearly distinguish Applicants' claimed dressing over the prior art, Applicants have amended claim 1 to recite that the enzyme acts to catalyze conversion of atmospheric oxygen to hydrogen peroxide for transport through the dressing to the skin for conversion to oxygen. Support for this amendment may be found, *inter alia*, at paragraph [0077] of Applicants' specification. Applicants provide herewith for the Examiner's consideration a document entitled "Oxygen Transport Function" (attached as **Exhibit B**), which describes the oxygen transport function and also provides an explanation

of why oxygen transport function would not occur with the dressings disclosed in Green. Applicants further submit that the structures disclosed in Powell also could not function to transport oxygen in the manner recited in Applicants' claim 1 as amended. More specifically, Powell teaches the use of an enzyme system comprising glucose oxidase and peroxidase (see, e.g., column 2, line 50 of Powell). Peroxidase activity utilizes the hydrogen peroxide produced by the oxidase to oxidize substrates - in this case, chromogenic substrates. Unlike the enzyme catalase, peroxidases do not release oxygen from hydrogen peroxide. Applicants provide herewith for the Examiner's consideration a document entitled "Insense Technology Briefing, October 10th 2007" (attached as **Exhibit C**), which describes the components and mechanism of the oxygen transport system present in Applicants' claimed dressings. Figure 7 shows that the presence of peroxidase suppresses oxygen transport. The specific teaching in Powell that peroxidase should be present thus means that this structure would not transport oxygen. Instead, the peroxidase is present in Powell for the purpose of utilizing any hydrogen peroxidase generated in the production of color. Importantly, the transportation of oxygen would be detrimental to this purpose. Applicants have surprisingly found that significant benefits arise from the use of a layered dressing with enzyme in a dried condition in the first dressing component.

By having the enzyme retained in a thin, dry film, all of the rehydrated active enzyme is concentrated at the point where it can do the most good by converting oxygen to hydrogen peroxide right at the interface between the source of atmospheric oxygen and the dressing. The system works significantly better in this mode, due to the high concentration of enzyme at this point and its absence from anywhere else in the system.

As the enzyme is highly concentrated in this location, it can be rehydrated quickly so that the beneficial oxygen transport function gets underway rapidly and efficiently. Applicants point out that Example 1 of the subject application demonstrates that, surprisingly, a dried enzyme layer begins to function more rapidly than a wet enzyme layer.

An additional benefit of Applicants' claimed dressing arises from the fact that the second dressing component carries the necessary water for hydrating the enzyme and does not rely on external sources of water such as biological fluids. Any system relying on biological fluids suffers from the problems of variability, unpredictability and the likely presence of interfering substances (such as catalase or hemoglobin). In contrast, Applicants' claimed dressing not only begins to function

more rapidly, but is self sufficient in water and optionally also in other ingredients, and can carry all necessary ingredients, none of which might be harmful. In addition, reactant concentrations, pH, etc. may be optimized.

For at least the above reasons, Applicants submit that the claimed dressing represents a significant advance over the prior art and therefore respectfully request that this rejection be withdrawn.

## **6. Conclusion**

Upon consideration of the foregoing, it will be recognized that Applicants have fully and appropriately responded to all of the Examiner's rejections. Accordingly, all claims are believed to be in proper form in all respects and a favorable action on the merits is respectfully requested. The Examiner is invited to contact the undersigned with any questions or concerns that may prevent this requested allowance.

Except for issues payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or to credit any overpayment to Deposit Account 50-0310. This paragraph is intended to be a constructive petition for extension of time in accordance with 37 C.F.R. 1.136(a)(3).

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